



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

GOBLE

Atty. Ref.: **2558-57**

Serial No. **10/036,500**

Group: **3739**

Filed: **JANUARY 7th 2002**

Examiner: **P. VRETTAKOS**

For: **AN ELECTROSURGICAL SYSTEM AND
METHOD**

* * * * *

AUG 17th 2004

RULE 132 DECLARATION OF COLIN C.O. GOBLE

I, Colin C.O. Goble, declare and state as follows:

1. I am the Director of Engineering at Gyrus Medical Ltd., the Assignee of the above-identified application.

2. I received a Bachelor of Science (Hons) Degree in Electrical Engineering from the University of Glamorgan, Cardiff, UK, and I have over 15 years of experience as an Electronic Engineer in the field of electrosurgical generators.

3. I have reviewed the Office Action issued in the above-identified application on May 20, 2004, and I make this Declaration in support of the response to such Office Action, which I understand is being filed in this application.

4. It is understood in the field of electrosurgery that there are two very different types of tissue treatment. The first is "Vaporization", which is an

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instantaneous tissue removal. In vaporization, an electrosurgical electrode is used such as to cause the destruction of cells, such that tissue in the region of the electrode is removed instantaneously. This process is usually carried out at high temperatures, often in excess of 300° C.

5. The second type of tissue treatment is "Lesion Generation". In this process, an electrosurgical electrode is brought into contact with tissue (often inserted into the tissue) and used to cause cell necrosis, while leaving the tissue in situ. Over the course of subsequent days or weeks, the dead cells are absorbed by the body. This process is usually carried out at lower temperatures, typically between 85° C and 120° C.

6. The term "Ablation" is frequently used in an imprecise manner, particularly in the patent literature, to describe the removal of tissue. For example, the patents cited by the Examiner, namely US 5,041,089 (Mueller), US 6,461,357 (Sharkey), US 6,149,620 (Baker) and US 5,419,312 (Arengerg), use the term ablation in a loose fashion to describe tissue removal. However, although ablation covers either vaporization or lesion generation, a man skilled in the art of electrosurgery will recognize that vaporization and lesion generation are separate techniques. They have different applications, and they are not interchangeable or obvious equivalents to one another.

7. The technique used in US 6,077,257 (Edwards) is clearly lesion generation. The electrodes are needle electrodes and the temperatures quoted are between 90° C and 120° C, and the RF energy is said to cause ablation "by means of cell death, dehydration or denaturation". The technique is also said to be

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capable of "filling fissures" or repairing "prolapsed or spasmodic muscle". This would clearly not be the case if instantaneous tissue removal were to be performed.

8. In contrast, the technique claimed in our amended claim 31 is clearly vaporization, requiring an instantaneous removal of the tissue constituting the tumor. This technique is not equivalent to or suggested by the lesion generation system of Edwards, and produces a very different result (i.e. the instantaneous removal of the tumor as opposed to a subsequent shrinkage thereof).

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

17th AUG 04
Date


Colin C.O. Goble